

REMARKS

Claims 25 and 28 have been amended to obviate the objections thereto.

Claims 1-8, 10, 11, 14, 16-18 and 20-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (4,932,965) in view of SU 513696.

Applicants respectfully traverse the rejection of the claims. The present invention relates to the use of a visual indicator associated with the strands of a suture system in which two strands are attached to the same needle and can be visually distinguished from each other. The prior Office Action has simply assumed this feature, providing no evidence in the prior art that would teach the recited combination.

The Office Action indicates that "SU '696 teaches that it is well known to use a system like this when attaching two biomaterials." Another copy of SU '696 is being enclosed herewith along with a translation thereof. A copy of the later published application by one of the same inventors (Meshalkin SU 827,047) is also enclosed (with abstract). First, these references specifically describe joining of tissue layers. There is no mention of joining "biomaterials" in either of these references and there is no disclosure relating to the more complex task of

mounting a prosthetic device such as a heart valve using the needle suture system of SU '696. The translation of SU '696 specifically states that "needles 2 are passing through both side(s) of incision at the portions of the tissues 3 and 4 which are to be joined." Of further importance is that both soviet references teach using a single thread mounted to all three needles which is subsequently cut. These references do not disclose or suggest attaching two separate suture strands to the same needle.

The rejection of the claims appear to be based at least in part on Ex parte Pfeiffer, 135 U.S.P.Q 31 (1962), where it was indicated that in order to be entitled to weight in method claims, the recited structure limitations "must affect the method in a manipulative sense...".

Applicant notes that claim 5 expressly recites a plurality of more than three needles connected by different suture strands using the visual indicator to identify each strand and then secure it to another strand. Method claims 1 and 21 have been amended to further clarify how the structure affects the method "in a manipulative sense." More specifically, the indicator of the strands are used in attaching the prosthetic device to the tissue, which is not the case in the facts of Ex parte Pfeiffer. The use

of a needle larger than the two attached sutures eases the insertion and reduces the risk of injury to the patient while inserting two separate strands with one needle.

Phillips does not teach or suggest the recited solution to this problem. Phillips utilizes different colors for different sutures 26, i.e., for different pairs of needles. By only using two needles connected by a single suture strand (see Fig. 2 where each suture 26 has opposite ends 28 and 30, which are the same color), Phillips does not have the problem of having the same color strands passing through the same hole. The alleged combination of Philips with SU 513696 is not obvious because there is no teaching that different color suture threads be attached to the same needle. Additionally, the SU 513696 reference does not disclose or suggest that the device is suitable for suturing a prosthetic implant. Consequently, it would not be obvious to employ a larger number of needles for securing a prosthetic implant that are interconnected by different indicators or colors. For example, no where is it suggested that alternating colors (claim 20) or three different colors be used in the cited references. The remaining references fail to suggest that a plurality of double stranded sutures be used for suturing a prosthetic device.

Claims 12 and 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the SU '696 patent and Phillips and further in view of Alpern. Claims 9 and 15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over SU '696 and Phillips '965 and further in view of Ablaza. Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over SU '696 and Phillips and further in view of Ovil.

Applicants respectfully traverse these rejections of the claims. The SU 513696 reference uses a single thread (1) with 3 needles with no way to distinguish between thread segments passing through the same hole (e.g. 6 and 7). Additionally, the SU 513696 reference relates to the joining of two tissue layers (3 + 4 in the text, apparently mislabeled in the figure) and does not disclose or suggest the use of the system for suturing a prosthetic device. However, Phillips does not suggest the solution provided by the present invention. Phillips teaches that different colored threads be attached to different pairs of needles. Phillips does not teach that two different threads, that are distinguishable from each other, can be attached to the same needle.

With respect to Ovil, there is no disclosure or suggestion of how to use a suture placement device with the claimed invention in

which at least three needles are connected by suture strands. Ovil teaches that "all suture 10 to be used in suturing the valve in place are applied by knotting one of their ends and passing the suture through a slot 14...". This Ovil system cannot be used with the present invention as it requires knotting of the ends before placement.

The rejection of claims is believed to be obviated in view of the above amendments and remarks. New claims 29-32 have been added for consideration. The use of six suture strands connecting seven needles is illustrated in Figs. 4 and 5 and described at pages 8-10 of the application, for example. The use of four needles is shown in Figs. 2 and 3A.

The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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